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REMARKSThe Claims

Claims 71-92 are currently under examination. Claims 71, 72, 82, 84 and 87 have been amended and Claim 74 has been cancelled without prejudice or disclaimer.

Examiner's Interview

Applicants' representative acknowledges the telephone interview with Examiner Blanchard on May 6, 2008 to discuss amendments to the claims. While an agreement on the claims was not reached, Applicants believe that the interview materially advanced prosecution of the application.

Withdrawal of Objections and Rejections

Applicants acknowledge the withdrawal of certain objections to the specification and rejections of the claims as set forth in paragraphs 7 and 8 of the present Office Action.

Rejections under 35 U.S.C. 112, second paragraph

Claims 71-72, 81-82 and 87-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claims 71 and 87 are deemed indefinite in the recitation of a "leukemia therapeutic agent" and Claims 72 and 87 are indefinite in the recitation of a "solid tumor therapeutic agent". Although Applicants believe that the terms "leukemia therapeutic agent" and "solid tumor therapeutic agent" are clear to one skilled in the art, Claims 71, 72 and 87 have been amended to recite a "therapeutic agent". Example 7, starting on p. 37, line 25 of the specification describes the conjugation of a therapeutic agent. It is believed that the rejection may be withdrawn.

Claim 82 is deemed indefinite in the recitation of a "monoclonal antibody or fragment thereof comprises a murine hypervariable region and a human constant and framework region". Although Applicants believe that the above phrase is clear to one skilled in the art, Claim 82 had been amended to recite "comprises murine hypervariable regions and human constant and framework regions".

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Example 3, starting on p. 31, line 12 of the specification describes antibodies with murine variable regions and human constant regions. It is believed that the rejection may be withdrawn.

Applicants note that the same rejection was also applied to Claim 81. It is believed that this was an inadvertent error by the Examiner as Claim 81 does not recite a "monoclonal antibody or fragment thereof comprises a murine hypervariable region and a human constant and framework region".

Claim 84 is deemed indefinite in the recitation of a "monoclonal antibody or fragment thereof comprises a human antibody". Although Applicants believe that the above phrase is clear to one skilled in the art, Claim 84 had been amended to recite a "monoclonal antibody or fragment thereof is a human antibody or fragment thereof". It is believed that the rejection may be withdrawn.

Rejections under 35 U.S.C. 112, first paragraph

Claims 71-92 are rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly does not enable claimed biological materials because there is no evidence that the materials are (1) known and readily available to the public; or (2) reproducible from the written description. In particular, the Examiner asserts that it unclear whether the human erythroleukemia cell line OCIM1 is known and publicly available or can be reproducibly isolated without undue experimentation.

Applicants wish to point out that a description of the cell line OCIM1 is found in Papayannopoulou et al. Blood 72, 1029-1038 (1988) cited at p. 9, lines 20-22 of the specification and attached hereto as Exhibit A. The reference describes methods for the generation of the erythroleukemia cell lines OCIM1 and OCIM2 and the characterization of their surface antigen profiles. As indicated in the specification on p. 29, line 24 to p. 30, line 2, one property of the OCIM1 cell line is the presence of stem cell factor (SCF) receptors on its surface. Based on the disclosures of the Papayannopoulou reference and the present specification, Applicants believe that OCIM1 cell line is enabled.

Without acquiescing to the rejection and solely to advance prosecution, Applicants have amended Claims 71, 72 and 76-78 to recite a monoclonal antibody or fragment thereof that binds "human c-kit" and inhibits the binding of human stem cell factor to "human c-kit". The specification fully enables such an antibody. Examples 1 and 2 of the specification describe methods for screening cell

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lines for the presence of SCF receptors and identify various cell lines that display SCF receptors on their surface. As noted in the specification at p. 30, lines 10-13:

The OCIM1 cells were used as an immunogen because of their high SCF receptor display, although any cell displaying SCF receptors could be used as an immunogen to elicit antibodies to the SCF receptor.

In addition, Example 5 starting on p. 35 of the specification describes an assay for the inhibition of stem cell factor binding to a stem cell factor receptor by the SR-1 antibody. The assay employs not only OCIM1 cells but also cells transfected with a gene expressing c-kit. Such an assay could be readily used by one skilled in the art to screen additional antibodies raised against immunogens described in Example 1 for their ability to inhibit binding of human stem cell factor to human c-kit.

Applicants maintain that the specification enables one skilled in the art to produce the claimed antibodies without undue experimentation.

Claim 74 is rejected under 35 U.S.C. 112, first paragraph, as the claim contains subject matter which allegedly does not satisfy the written description requirement. Claim 74 recites a monoclonal antibody of the methods of Claims 71 and 72 which "competes with the monoclonal antibody produced from the hybridoma cell line ATCC No. HB 10716 for binding to OCIM1 cells". It is alleged that support for the subgenus of antibodies is not found in the specification and therefore new matter has been introduced.

Without acquiescing to the rejection and solely to advance prosecution, Applicants have cancelled Claim 74 without prejudice or disclaimer thereby rendering the rejection moot.

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CONCLUSION

It is believe that Claims 71-73 and 75-92 are in condition for allowance and the application may proceed to issuance. The Examiner is encouraged to call the undersigned to discuss any outstanding issues that may remain.

Respectfully submitted..



Robert B. Winter
Attorney/Agent for Applicant(s)
Registration No.: 34,458
Phone: (805) 447-2425
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Please send all future correspondence to:
21069
US Patent Operations/RBW
Dept. 4300, M/S 28-2-C
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799